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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,833	01/04/2002	Javier Alarcon	P-5074	9548

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,833

Applicant(s)

ALARCON ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-16 of copending Application No. 2002/0130167 and 2003/0134346 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a biosensor using a mutated glucose binding protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hellinga.

Hellinga teaches a glucose biosensor comprising a genetically engineered glucose binding protein (GBP hereafter) that has been read on the claimed mutated binding prot12ein. There are luminescent labels, acrylodan and IANBD (see figures 2-3 and col. 6 lines 41+), covalently attached to the GBP that emit light at a wavelength greater than 600nm. Column 9 lines 6+ teach cysteine mutations at the claimed "152" position.

Claims 1-7, 10-16 and 19-20 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lakowicz et al.

Lakowicz et al. teaches an engineered or modified protein that can be used for the detection of glucose in a biosensor. Column 5 lines 27+ teach the placing a cysteine residue at position "182" and covalent attachment which is identical to that claimed. Column 5 lines 4+ teach use of the claimed labels such as acrylodan, fluorescein, rhodamine, etc. Column 11 lines 35+ teach use of a PVA film.

Claim Rejections - 35 USC § 103

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al.

See Lakowicz et al. *supra*.

Lakowicz et al. are silent to the claimed siloxanes condensed with at least one water-soluble organic polyol component and the claimed silicone additives.

The court decided In re Leshin (125 USPQ 416) that selection of a polymeric material based upon its suitability of intended use is within the skill of the art.

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Siloxanes and silicone materials are widely used in the art because of their inert properties. It would have been within the skill of the art to modify Lakowicz et al. and use the above siloxane and silicone materials to gain the above advantages and further in view of Leshin as selection of a material based upon its suitability of intended use.

Claims 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellinga alone or in view of Lakowicz et al.

See Lakowicz et al. and Hellinga supra.

Hellinga is silent to the claimed polymer support, the claimed siloxanes condensed with at least one water-soluble organic polyol component and the claimed silicone additives.

The court decided In re Leshin (125 USPQ 416) that selection of a polymeric material based upon its suitability of intended use is within the skill of the art.

Polymers, siloxanes and silicone materials are widely used in the art because of their inert properties. It would have been within the skill of the art to modify Hellinga and use the above siloxane and silicone materials to gain the above advantages and further in view of Leshin as selection of a material based upon its suitability of intended use. Lakowicz et al. above teaches it is known to place a glucose sensor on a PVA film. PVA is inexpensive, inert and readily available. It would have been within the skill of the art to modify Hellinga in view of Lakowicz et al. and use a PVA support to gain the above advantages.

Response to Arguments

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Applicant's arguments filed 2/4/04 have been fully considered but they are not persuasive.

Applicants' traverse the obviousness-type double patenting rejection over the '167 claims on the basis these claims teach attachment of the mutated protein to a sensor surface. The claims of this application are sufficiently broad that "matrix entrapping or encapsulating" has been read on the sensor surface. Alternatively, the instant claims are open language (e.g. comprising) and do not exclude the additional sensor surface claimed in the '167 application.

Applicants' traverse the obviousness-type double patenting rejection over the '346 claims because these claims do not specify a permeable matrix. It is inherent the '346 claims have a permeable matrix or else the analyte could not contact the biosensor.

Applicants' traverse the 35 USC 102 rejection over Hellinga on the basis it fails to teach a polymer support, the claimed siloxanes and the claimed silicone additives. These claims only require the polymer support that has been read on the teachings in column 5 that teach the protein bound in a sensor.

Applicants' traverse the 35 USC 102 rejection over Lakowicz on the basis this reference fails to meet the analyte permeable encapsulating matrix. The Office maintains col. 11 lines 35+ of Lakowicz teach containment of the mutated protein with the PVA film.

In response to applicant's arguments against the references individually under 35 USC 103, one cannot show nonobviousness by attacking references individually where

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the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
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